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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,571	12/27/2001	Shuyuan Zhang	29853/37702	9714

7590 07/11/2005
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EXAMINER

MOSHER, MARY

ART UNIT PAPER NUMBER

1648

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/033,571

Applicant(s)

ZHANG ET AL.

Examiner

Mary E. Mosher, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 70-128 is/are pending in the application.
- 4a) Of the above claim(s) 99-128 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 70-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/13/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Claims 99-128 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/23/2004.

Terminal Disclaimer

The terminal disclaimer filed on 4/13/2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6194191 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

Claims 70-98 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims were rejected as indefinite for because they are drawn to a process of making an adenovirus composition "for therapeutic use," and the specification does not make clear specification what characteristics make an adenovirus composition suitable "for therapeutic use", or draw a line which distinguishes between a composition "for therapeutic use" and a composition unsuitable for that intended use. Applicants argue that this recitation would be understood by those of skill in the art because the level of purity required for therapeutic compositions is established by regulatory agencies such as the FDA, and cites for example the current proposed guidelines for pyrogenicity/endotoxin for human gene therapy. However, this

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argument is flawed. The patent statutes require an application to be full and complete as of the filing date. The standards for therapeutic acceptability are critical for establishing the metes and bounds of the claimed invention, and one is not able to determine these metes and bounds by reading the specification. There is no mention of FDA requirements in the specification as filed, no incorporation by reference to any standard, and no indication on the record that those skilled in the art were knowledgeable about FDA purity standards for therapeutic use of adenovirus as of the filing date of this application or the filing dates of the priority applications. The FDA standards cited in the response are "Draft Guidance.. distributed for comment purposes only," and therefore are clearly open to change. Furthermore the FDA document was issued nearly three years later than the instant filing date, and 8 years after the earliest claimed priority date. Therefore, the record as a whole does not indicate routine knowledge in the art as to what purity was considered acceptable for therapeutic use as of either the application filing date, or the any of the earlier claimed priority dates. Since this is an essential feature defining the invention, it is maintained that the claims are indefinite.

Claim Rejections - 35 USC § 103

Claims 70, 72, 73, 75-77, 80-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shabram et al 5,837,520 in view of Perrin et al (Vaccine 13(13):1244-1250, 1995), Garnier et al (Cytotechnology 15:145-155, 1994), and/or Nadeau et al (Biotechnology and Bioengineering 51:613-623, 1996), for reasons of record. Applicant argues that the secondary references do not provide motivation to modify the Shabram

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method, and even if the secondary references would have taught the modification so as to improve yields it would not have been obvious to do so to improve the purity of the resultant product as provided by the present invention. In regard to improved purity, applicant is arguing limitations which do not appear in these claims, since the rejection provides reasons to believe that the Shabram method produces products meeting the specific purity criteria recited in these claims. In regard to motivation, Nadeau explicitly states that large culture volumes are required to produce sufficient pfu of adenovirus for preclinical trials, see the Introduction. Nadeau also states that the recombinant protein production system chosen "has the advantage of providing a simple, albeit indirect, measure of virus production, since PTP1C and viral capsid proteins are both controlled by the same promoter." Therefore motivation existed to use similar methods to optimize virus production, and reasonable expectation of success.

Applicant argues that the rejection is essentially identical to that overcome in US 6194191 and should be withdrawn for similar reasons. However, none of the instant claims recite the specific process steps which overcame the rejection in the patented case.

Claims 78, 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shabram et al in view of Perrin et al, Garner et al, and/or Nadeau et al as applied to claims 70, 72, 73, 75-77, 80-97 above, and further in view of Morris et al (Williamsburg BioProcessing Conference, Nov. 18-21, 1996) or Gilbert (Williamsburg BioProcessing Conference, Nov. 18-21, 1996), for reasons of record.

Conclusion

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7/7/05



MARY E. MOSHER, PH.D.
PRIMARY EXAMINER